DenOptix® QST

Operator and Service Manual

Manuale dell'Operatore e Servizio

Manuel de l'Opérateur et de Service

Gebrauchsanweisung

Manual del Usuario y de Servicio

Phosphor Plate Technology

GENDEX®

Operator and Service Manual

English

Inglese

Anglais

Englisch

Inglés

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This manual in English is the original version.

Introduction

DenOptix® QST "Quad Speed Technology" System by Gendex®

DenOptix QST Intraoral (FMX) System

DenOptix QST Extraoral (E/O) System

DenOptix QST Intraoral and Extraoral System (Combo) System

Congratulations! Your decision to add the DenOptix QST System to your practice represents a wise investment for the future of your practice.

The DenOptix QST is a revolutionary product designed to completely replace traditional X-ray film and film processors. This system, built on phosphor imaging plate technology, offers the following benefits:

- Diagnostic quality images — every time.
- Lowers the price of dental imaging by eliminating the need for costly film, chemistry and film processors.
- Imaging plates are reusable.
- Saves critical time vs. using processing systems. DenOptix QST will process 4 bitewings in under 30 seconds and a FMX will process 20 images in less than 4 seconds per image. Panoramic images can be obtained in less than 80 seconds. A cephalometric image can be obtained in less than 80 seconds.
- Significant reduction of X-ray dose as compared to D-speed film.
- It works with your current X-ray generating equipment. There is no need to purchase new equipment.
- Reduces the hassles associated with the waste stream disposal.

For over 50 years, dental professionals have relied on Gendex to provide X-ray equipment of the highest technology and quality. From our classic AC intraoral units to the software-driven Orthoralix® panoramic, we are dedicated to providing products with the features and high quality you desire. As you enjoy using the new DenOptix QST system, you are taking advantage of our 50 years of manufacturing expertise in the dental industry.

Our motto speaks for itself: Gendex. Imaging Excellence.

Technical support

Call your local Gendex location. For a phone number, please refer to page 62.

Supplies and replacement parts

To order supplies or replacement parts for your DenOptix QST, contact your local Gendex equipment dealer. If your dealer is unable to assist you, call the Gendex location nearest to you.

1

Indications for use

The DenOptix QST is intended for use as a digital dental radiography system using X-ray recording media (phosphor imaging plates) for radiographic diagnostic intraoral and extraoral exposures providing interactive CRT retrieval, viewing and processing of stored computed radiographic images.

The system includes reusable photostimulable phosphor imaging plates, a laser diode scanner device and optical reader components, communications electronics and software, and various peripheral accessories.

2

Contraindications

There are no contraindications for use.

3

Safety requirements

3.1 Important information

It is important that all personnel who will operate the DenOptix QST System read and understand this manual before operating the device. All personnel should follow all warnings and cautions as outlined in Section 3.2, for their safety and the safety of others around them.

3.2 Warning and caution statements

In this manual, the following definitions apply for all WARNINGS and CAUTION statements:

Warnings: Any operation, procedure or practice, which, if not strictly observed, may result in injury or long-term health hazards to personnel or patients.

Cautions: Any operation, procedure or practice, which, if not strictly observed, may result in destruction of equipment or loss of treatment effectiveness.

Warnings

Should be used only by trained professional.
Federal law restricts the sale of this device to physicians, dentists and dental professionals only. Use of this device in procedures other than those described in this manual may result in injury.

Do not open the device to service it.
None of the internal parts of the scanner are user serviceable. The only user serviceable parts of the system are outlined in Section 7.2. If there is a service problem, call your qualified Gendex dealer or the Gendex representative nearest you.

Do not place DenOptix QST near:

- X-ray equipment that is constantly energized (e.g., devices such as fluoroscopes which are energized when not in use)
- Magnetic resonance imaging systems
- Large motor/electric generators

There is potential for electromagnetic interference between devices when using electronic equipment. International standards exist to minimize this potential.

DenOptix QST has been tested against and complies with the international standard EN 60601-1-2, Medical Electrical Equipment - General Requirements for Safety - Collateral Standard; Electromagnetic Compatibility Requirements and Tests, class A.

Use only grounded electrical connections.
Connect the DenOptix QST scanner to a grounded electrical outlet between 100-240 volts AC.

Do not reuse the barrier envelopes.
Once used within the oral cavity, the barrier envelopes are bio-contaminated and should NEVER be reused. Please dispose of in accordance with Section 7.4.

Imaging plates are toxic!
Never place an imaging plate in a patient's mouth without enclosing it first in a completely sealed barrier envelope. If a patient swallows an imaging plate, contact a physician immediately. The physician must remove the imaging plate. Do not use cracked, bent or chipped imaging plates.

Never open or override the lid lock when the scanner is in use or plugged in.
The scanner lid will lock during operation. In case of power failure, unplug the scanner and open the lid by depressing the lock mechanism as indicated in Section 7.3.

Never use imaging plates with patients that might chew or swallow them.
If the patient bites or chews the plate and damages the protective barrier envelope, rinse the patient's mouth with a large amount of water. If the patient manages to swallow any of the blue surface of the plate, contact a doctor immediately.

The DenOptix QST scanner is a Class 1 laser device.

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure. A fail-safe switch in the carousel well and cover keeps the laser inactive as long as the cover is open. Only a trained technician from a qualified Gendex dealer should remove the cover from the scanner. Direct eye contact with the output beam from the laser may cause serious damage and possible blindness.

Caution statements

Reduce the exposure time on your intraoral X-ray unit.
The DenOptix QST System is designed to produce high quality, diagnostic images at reduced radiation levels. To get the maximum benefit, we recommend that the exposure be reduced as outlined in Section 5.1.

Completely erase the imaging plates.
Before reusing an imaging plate, place it with the blue or white surface up facing a bright light source for at least two (2) minutes as described in Section 5.2.

Mount the imaging plates under low light conditions.
Mount the imaging plates to the carousel under low light conditions as described in Section 5.4. Exposure to direct sunlight or direct indoor lighting will erase the information stored on the imaging plate.

Do not place scanner on or next to a radiator or water source.
Excessive heat or small amounts of water may damage the scanner's electrical components.

Do not use in the presence of flammable anesthetics mixtures.

Do not autoclave the imaging plates.
Autoclaving will damage the imaging plate. If this happens, discard the imaging plate and replace it with a new one. If an imaging plate becomes contaminated, follow the procedure described in Section 5.6.

Do not leave unscanned, exposed imaging plates in light.
Leaving unscanned, exposed imaging plates in light will cause severe loss of image quality. If left exposed for long time, or to bright light, the image may be erased entirely.

Do not scratch the imaging plates.
When handling the imaging plate, do not touch the active side (blue or white) any sharp object that might scratch the surface. Do not lay unprotected imaging plates face down.

Pre-installation information and recommendations

4

4.1 Purpose of the manual

The instructions contained in this manual should be carefully followed for safe, trouble-free and effective equipment use.

This manual provides the essential information necessary for the installation, operation and routine care of the DenOptix QST System. The detailed instructions for the imaging software associated with the scanner can be found in the Imaging Software User Manual and Installation Guide. Important instructions for personnel who have been trained in intraoral and panoramic radiography are contained in this manual. This manual is not to be used as a replacement for training in dental radiography.

4.2 Abbreviations and explanations of symbols

AC	Alternate current
DC	Direct current
Hz	Hertz; cycles per second
MHz	Millions of hertz
LED	Light emitting diode
kVp	Peak voltage in thousands of volts
IP	Imaging plates
CD-ROM	Compact disc, read-only
pan	Panoramic

ceph	Cephalometric
I/O	Intraoral
Combo	Combination system capable of scanning both I/O and panoramic imaging plates
TIFF	Tagged image file format
LP/mm	Line pairs per millimeter
PSP	PhotoStimulable Phosphor
D.P.I.	Dots per inch
CPU	Central processing unit (your computer)
IEC	International Electrotechnical Commission
|	Power on
O	Power off
	Green indicator, ready
	Yellow indicator, scanning
	Red indicator, error in scanning; refer to operators manual
	High voltage
	Laser radiation
RAM	Random access memory
MB	Mega bytes
GB	Giga bytes
USB	Universal serial bus
CE	The CE symbol ensures that the product herein specified meets the applicable provisions of the European Council Directives.

4.3 Physical description

The DenOptix QST system has several configurations. Even if the basic hardware is the same, DenOptix QST is provided with different licenses for scanning different types of plates, according to the chosen model. See the following table for a complete list of components for each model. At the interception of "models" (columns) and "components" (rows) you'll see the quantity supplied for that item. If no quantity is specified, that item is optional and it can be purchased using the catalog # shown in the same row.

The Intraoral (FMX) and Extraoral (EO) models are upgradeable to the Combo (COMBO) system. Contact your local Gendex representative for details. In addition, the Extraoral and Combo systems can be upgraded to Cephalometric by ordering the catalog number listed on the following table.

Note: Buying some components such as imaging plates or carousels may not allow you to use them without License from Gendex. Upgrade Kits are available for the following: FMX series to upgrade to a Combo system, EO series to Combo system, and EO or Combo series to Ceph.

Customer Supplied Components

- Bottle of anhydrous isopropyl alcohol for cleaning imaging plates
- Computer system as described in Section 4.4
- Monitor for viewing

Table of models and components

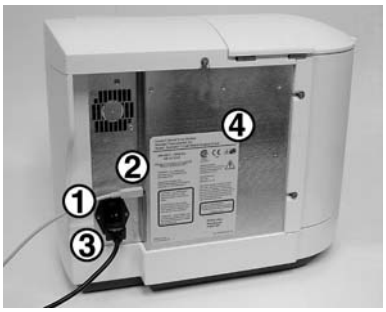
Components	Catalog #	FMX	Extraoral (Panoramic)		Combo		Cephalometric Upgrade	
		DOQFMX	DOQEO512	DOQEO1530	DOQCOMBO512	DOQCOMBO1530	DOQCEPH810	DOQCEPH1824
DenOptix QST Laser Scanner		1	1	1	1	1	-	-
Embedded Software License for Full-Mouth Series		1	-	-	1	1	-	-
Embedded Software License for Limited Intraoral Images		-	1	1	1	1	-	-
Embedded Software License for Panoramic Images		-	1	1	1	1	-	-
Embedded Software License for Cephalometric Images		-	1	1	1	1	-	-
Intraoral Carousel (FMX)	DOQFMXCAR	1	-	-	1	1	-	-
Extraoral Caousel (EO)	DOQEOCAR	-	1	1	1	1	-	-
Cephalometric Carousel (CH)	DOQCHCAR	-	-	-	-	-	1	1
Panoramic Imaging Plate 5x12in	DOIPQ5x12	-	1	-	1	-	-	-
Panoramic Imaging Plate 15x30cm	DOIPQ15x30	-	-	1	-	1	-	-
Cephalometric Imaging Plate 8x10in	DOIPQ8x10	-	-		-	-	1	-
Cephalometric Imaging Plate 18x24cm	DOIPQ18x24	-	-		-	-	-	1
Intraoral Size 0 Imaging Plates, pack of 2	DOIPS00	-	1	1	1	1	-	-
Intraoral Size 1 Imaging Plates, pack of 2	DOIPS01	-	-	-	-	-	-	-
Intraoral Size 2 Imaging Plates, pack of 4	DOIPS02	5	2	2	5	5	-	-
Intraoral Size 3 Imaging Plates, pack of 1	DOIPS04	-	-	-	-	-	-	-
Intraoral Size 4 Imaging Plates, pack of 2	DOIPS03	-	-	-	-	-	-	-
Size 0 barriers, pack of 100	DOBES00	-	1	1	1	1	-	-
Size 1 barriers, pack of 100	DOBES01	-	-	-	-	-	-	-
Size 2 barriers, pack of 100	DOBES02	5	2	2	5	5	-	-
Size 3 barriers, pack of 100	DOBES03	-	-	-	-	-	-	-
Size 4 barriers, pack of 50	DOBES04	-	-	-	-	-	-	-
Dark Box for plate transfer	DOBOX	1	1	1	1	1	-	-
VixWin Imaging Software	VIXWINPRO	1	1	1	1	1	-	-
User Manual	M010-004WWE	1	1	1	1	1	-	-
USB Cable, 6ft or 2m	126-038861	1	1	1	1	1	-	-
Power Cord		1	1	1	1	1	-	-

DenOptix QST laser scanner

Figure 4–1 Scanner front view

1) Carousel well and lid. The lid has a locking mechanism that engages during scanning and loss of power (see Section 7.3 or handling procedure). The carousel, with imaging plates attached, is inserted into the carousel well for scanning. The carousel lid must be in the closed position prior to scanning. The scanner will not operate with the lid open.
2) LED indicator lights with graphic symbols.
   The lights show the current status of the system.
   Green — Ready to scan
   Yellow Blinking – Scanning
   Red — Error

Figure 4–2 Scanner rear view



1) DenOptix QST scanner power entry module with switch and fuses
2) USB 2.0 connector. A USB 2.0 cable (provided) connects the DenOptix QST scanner to the CPU's USB 2.0 port.
3) Power cord socket. The power cord (provided) will be connected from this point to a grounded main outlet.
4) Scanner label

Scanner label

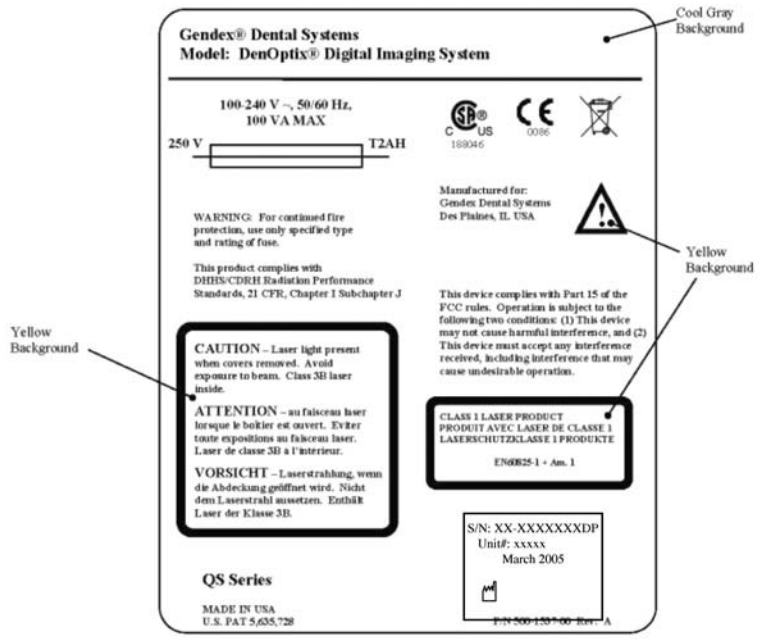
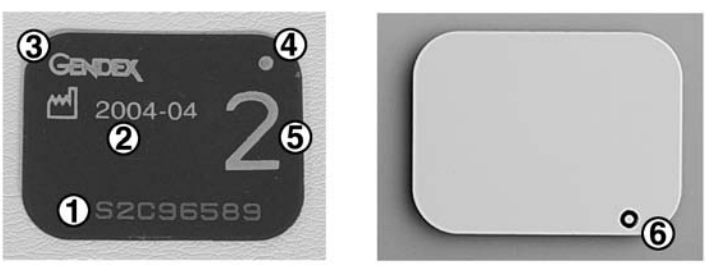

Gendex® Dental Systems
Model: DenOptix® Digital Imaging System
Cool Gray Background
100-240 V ~, 50/60 Hz,
100 VA MAX
250 V
T2AH
188046
0086
Manufactured for:
Gendex Dental Systems
Des Plaines, IL USA
WARNING: For continued fire protection, use only specified type and rating of fuse.
This product complies with DHHS/CDRH Radiation Performance Standards, 21 CFR, Chapter I Subchapter J
This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesirable operation.
Yellow Background
Yellow Background
CAUTION – Laser light present when covers removed. Avoid exposure to beam. Class 3B laser inside.
ATTENTION – au faisceau laser lorsque le boîtier est ouvert. Eviter toute expositions au faisceau laser. Laser de classe 3B à l'interieur.
VORSICHT – Laserstrahlung, wenn die Abdeckung geöffnet wird. Nicht dem Laserstrahl aussetzen. Enthält Laser der Klasse 3B.
CLASS 1 LASER PRODUCT
PRODUIT AVEC LASER DE CLASSE 1
LASERSCHUTZKLASSE 1 PRODUKTE
EN60825-1 + Am. 1
S/N: XX-XXXXXXXDP
Unit#: xxxxx
March 2005
QS Series
MADE IN USA
U.S. PAT 5,635,728

Figure 4–3 Intraoral imaging plates

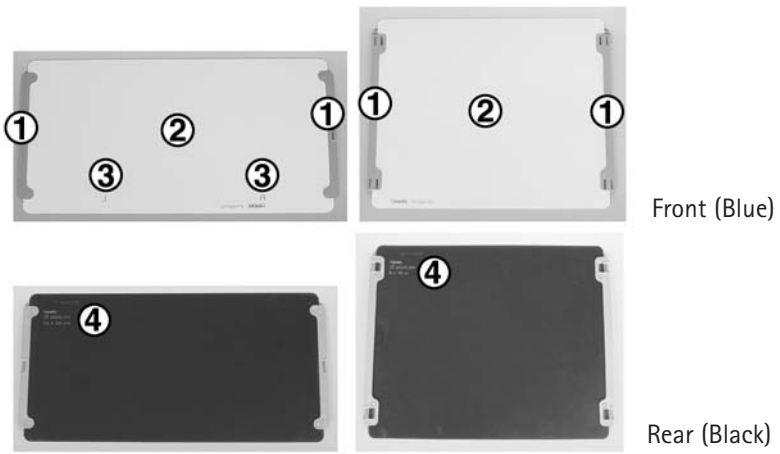


Rear (Black) Front (Blue)

1) IP serial number for tracking purposes
2) Date of manufacture
3) Available from Gendex Dental Systems
4) Solid orientation dot
5) IP size indicator. Shows the equivalent film size
6) Orientation circle. Visibly shows on final radiograph for faster orientation

Figure 4-4 Panoramic and cephalometric imaging plates

Panoramic **Cephalometric**



1) Plastic mounting strips used to hold panoramic imaging plate onto the carousel

2) Active imaging area, white color

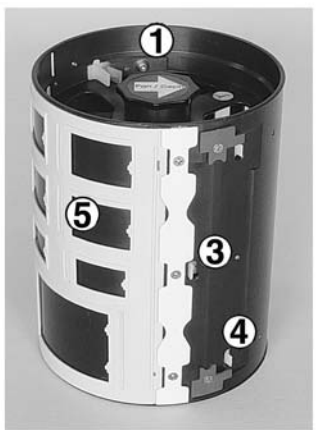
3) Patient left (⅃) and right (Я) side indicators

4) General information that includes:

- Available from Gendex
- Date of manufacture
- Imaging plate size
- IP serial number

Figure 4-5 Carousels

Intraoral (QFMX)



Extraoral QEO/Ceph (QCH)

1) Top of the carousel. For the EO/CH carousels, the knob will be positioned based upon whether or not a Pan or Ceph is being scanned. If a Pan or Ceph is loaded, turn the knob towards the mark indicating a Pan or Ceph. If no Pan/Ceph plate is loaded, rotate the knob to the "no Pan or Ceph" position.
2) I/O imaging plate holders. The intraoral carousel can hold up to 39 I/O imaging plates at one time: 20 size 2, 9 size 1, 8 size 0, 2 size 3.
3) Panoramic imaging plate retaining device. The panoramic carousel can hold either the 5x12 in or the 15x30 cm imaging plate.
4) Cephalometric imaging plate retaining device can hold either 8x10 in or 18x24 cm.
5) I/O imaging plate holders on the back of the Extraoral (EO) and Ceph (CH) carousel. The carousel can hold up to four size 2, two size 0 and one size 4 imaging plates.

Figure 4-6 Disposable barrier envelopes

Front (Blue)

Back (Clear)

1) The front of the barrier envelope is blue. This is the side that should face the X-ray tube.
2) Barrier envelope adhesive strip. When this is removed, the envelope can be sealed and provides protection from cross-contamination

4.4 Computer requirements

	Minimum Computer Requirements	Recommended
CPU Speed	800 MHz	Pentium 4 2.4 GHz
Operating system	Microsoft® Windows® 2000 /XP Pro SP2	Microsoft® Windows® XP Pro SP2
RAM	128 MB	256+ MB
Hard Drive	6 GB	40+ GB[1]
USB port	USB 2.0	USB 2.0
Monitor	S-VGA with 0.25mm/0.26mm dot pitch	S-VGA with 0.25mm/0.26mm dot pitch
Video Display Adapter	4 MB RAM, 800 x 600 display, true color	8+ MB RAM, 1024x768 true color
Keyboard, Mouse	Standard	Standard
Backup Device	Highly recommended	
Printer	Recommended (see appendix C)	

[1]To be evaluated based on the number of images taken, and the image file size used by the imaging software.

4.5 Electrical requirements

Voltage	100-240 V AC 50/60 Hz power supply auto-senses the input voltage.
Power	110 watts maximum
Power Cord	Standard line cord provided (Medical Grade for 115V)

4.6 Compliance to standards

The DenOptix QST System conforms to the following standards:

Standard	Title
UL 60601-1	Medical Electrical Equipment, Part 1: General requirements for safety
21 CFR Chapter I Subchapter J	Performance Standard for Light-Emitting Products
MDD 93/42/ECC	European Medical Device Directive (CE Mark)
CAN/CSA-C22.2 No. 601.1	Medical Electrical Equipment, Part 1: General requirements for safety
IEC 60601-1	Medical Electrical Equipment, Part 1: General requirements for safety
IEC 60601-1-2	Medical Electrical Equipment, Part 1: General requirements for safety- Collateral standard; Electromagnetic Compatibility
IEC 60825-1	Safety of Laser Products
ISO 13485	Medical devices- Quality management systems
ISO 14971	Risk Analysis

4.7 Installation

The DenOptix QST System is designed to be installed by a qualified equipment professional from your local dental dealer. Ask your local dental dealer for more information.

We do not recommend that an untrained person try to install and configure the system.

4.8 Site selection

The DenOptix QST scanner can be located almost anywhere in the dental office. The site you pick should have:

- Subdued lighting conditions. You should have the ability to turn down/off the lights and block sunlight with blinds. The area to be used for mounting imaging plates should not exceed 20 lux as measured on a light meter. This will give you about one minute to mount all of your imaging plates without encountering excess signal fading. If you cannot measure the light in the room where you wish to mount the imaging plates, you should turn off the room lights, close all blinds and leave the door open just enough so that you can see to mount the imaging plates. This should make the light level about 10-20 lux. If you need more than one minute, refer to appendix B.
- A stable, flat countertop large enough to hold the scanner plus provide a working area. We suggest a minimum of 189x369 in. (46x92 cm). The computer does not need to be on the countertop, but must be within the length of the USB 2.0 cable (9ft or 3m provided). The countertop must be able to hold the weight of the unit or a minimum of 60 lbs (27 kg).
- Access to a standard grounded electric outlet.
- Enough room to allow the operator to mount imaging plates and use the computer effectively.
- Do not position the DenOptix QST scanner in a dusty environment. Excessive dust levels can result in additional scanner service, beyond normal service intervals.

If you choose to put the system in your darkroom, please prepare the site by:

- Removing all old film processing equipment and plumbing.
- Remove the safelight filter and adjust the intensity of the light by lowering the bulb wattage until the intensity of the light around the scanner is 20 lux or less.
- We recommend that you keep the light off and the door open when mounting imaging plates to the carousel. The light from the open door will allow you to see enough to mount the imaging plates but will not adversely effect the image.

4.9 Unpacking the unit

The DenOptix QST System is shipped in one box. Completely unpack the box and save it in a safe, dry location. You may need to repack the unit for shipping if you ever encounter a maintenance outage, or relocate your office.

Inventory the contents of the box according to the "Table of Models and Components" (Section 4.3) and ensure that you have all the components for your DenOptix QST system as they're listed in the Table. If any items are damaged or missing, contact your dental dealer immediately.

Figure 4-7
Scanner, 1 each

Figure 4-8
Intraoral Carousel 1 each (FMX and Combo units)

Figure 4-9
EO/CH Carousel 1 each (EO, Combo units, and Ceph upgrade)

Figure 4-10
Disposable Barrier Envelopes 500 Size 2 (FMX and Combo units), 200 Size 2 (EO units)

Figure 4-11a
Size 0 Imaging Plates, 2 each (EO and Combo units)

Figure 4-11b
Size 2 Imaging Plates, 20 each (FMX and Combo units), 8 each (EO units)

Figure 4-12
15x30 cm or 5x12 in Imaging Plate, 1 each (EO and Combo units)

Figure 4-13
18x24 cm or 8x10 in Imaging Plate, 1 each (Included with purchase of Ceph kit)

Figure 4-14
Power Cord, 1 each

Figure 4-15
User Manual and Installation Guide (Software and Hardware), 1 each

Figure 4-16
USB 2.0 cable (6 ft, 2 m) 1 each

4.10 Hardware setup and connections

NOTE: Before you start the hardware setup, ensure that you have an acceptable computer as outlined in Section 4.4. The computer must have a USB 2.0 port available.

Step 1: Pick a location using the guidelines from Section 4.8.

Step 2: Set up the computer and monitor per the manufacturer's recommendations. Use an ergonomic setup to minimize repetitive motion injuries.

Step 3: Turn the power on to the monitor and computer.

Step 4: Connect the device end of the USB 2.0 cable to the USB 2.0 connector on the back of the DenOptix QST scanner. Connect the scanner to a grounded power outlet. Make sure the other end of the USB 2.0 cable is connected to the USB 2.0 port on the computer.

Step 5: Connect the computer to a network if desired. Refer to your Imaging Software User Manual and Installation Guide for more information on how to configure the Imaging Software in a network.

Step 6: Turn the power on the scanner. The green light on the scanner should be lit at this time. If it is not, follow the trouble shooting guidelines in Section 7.3.

Step 7: After the Windows operating system is loaded, a message indicating that a "New Hardware" has been found will appear. Follow the on-screen instructions to finalize the installation.

4.11 Network installation

Refer to your network/computer professional for network installation, configuration and maintenance. Refer to your Imaging Software User Manual and Installation Guide for more information on how to configure the Imaging Software in a network.

5

System operating instructions

5.1 Preparing your current X-ray equipment

The DenOptix QST System produces X-ray images of high quality and low noise yet offers a dose reduction in intraoral surveys up to 80% of the dose required for D-speed intraoral film. More details on how this technology works can be found in appendix A. Almost any intraoral or panoramic X-ray unit can be used with the DenOptix QST system. There is no need to purchase a new one.

The imaging plates produce excellent diagnostic images over a wide range of exposures. With the DenOptix QST system, it is possible to get diagnostic images at the same exposure time you use for X-ray film or as much as 80% reduction of the dose required for D-speed film. This means that it is more difficult to over- or under-expose an image. We recommend, however, that you start with the exposure times outlined in the table below.

Intraoral equipment

Exposure times indicated hereunder are estimates that must be verified and adjusted depending on specific and actual local conditions, e.g. supply voltage, X-ray tube yield, timer accuracy, beam filtration, etc.

Intraoral equipment suggested exposure times, in seconds and impulses

DC SUPPLY AC SUPPLY	50 kV	60 kV	60kV 65 kV	65 kV 70 kV	70 kV 75 kV
Lower incisor/cuspid	0.32 sec. 19 impulses	0.25 sec. 15 impulses[1]	0.16 sec. 20 imp.	0.16 sec. 10 imp.	0.12 sec. 7 imp.
Lower premolar	0.40 sec. 24 imp.	0.32 sec. 19 imp.	0.16 sec. 25 imp.	0.16 sec. 10 imp.	0.12 sec. 7 imp.
Lower molar	0.50 sec. 30 imp.	0.40 sec. 24 imp.	0.20 sec. 32 imp.	0.20 sec. 12 imp.	0.16 sec. 10 imp.
Upper incisor/cuspid	0.40 sec. 24 imp.	0.32 sec. 19 imp.	0.16 sec. 10 imp.	0.16 sec. 10 imp.	0.12 sec. 7 imp.
Upper premolar	0.50 sec. 30 imp.	0.40 sec. 24 imp.	0.25 sec. 15 imp.	0.20 sec. 12 imp.	0.16 sec. 10 imp.
Upper molar	0.64 sec. 38 imp.	0.50 sec. 30 imp.	0.32 sec. 19 imp.	0.25 sec. 15 imp.	0.20 sec. 12 imp.

Reference conditions:

- Adult patient
- Anodic current 7 mA.
- Source to Detector Distance SSD = 250 mm (10 inches)
- Total (inherent) filtration 2 mm Al equip.

Unless the image is grossly over- or under-exposed, image density can be corrected by subsequent software processing (contrast/brightness — see Imaging Software User Manual and Installation Guide).

[1] One impulse is equal to .017 sec. at 60 Hz. The recommended number of impulses can be adjusted as necessary for proper exposure, resulting in adequate image density and contrast and low noise gratuity.

Panoramic/cephalometric equipment

The DenOptix QST system requires no adjustments to the panoramic/cephalometric exposure settings (kV, mA or time). The DenOptix QST system can be used with almost any existing panoramic/cephalometric unit, regardless of age or manufacturer.

The use of a cassette without an intensifying screen is highly recommended. If you choose to use a cassette with an intensifying screen, you must at a minimum remove the front screen. If the intensifying screens are not removed, you will get a low quality image due to the shielding effect from a decreased dose reaching the imaging plate. To remove the intensifying screens, follow the directions below.

- If you have a soft vinyl cassette, simply remove both intensifying screens from the cassette.
- If you have a hard sided cassette, remove intensifying screens (these are usually glued).
- Cassettes without intensifying screens are also available from Gendex.

Contact your local dental dealer or the panoramic/cephalometric equipment manufacturer for additional assistance.

5.2 Erasing the imaging plate

Imaging plates should be erased just prior to use. Scanning an imaging plate does not erase all the image information. To completely erase the imaging plate, expose the front surface (blue or white in color) to direct, intense light for 2 minutes. Fluorescent light is highly recommended.

An effective way to erase the imaging plate is to use a lightbox such as the RINN® Universal Viewer. We recommend fixing the lightbox under a cabinet. Make sure to lay the imaging plate down with the ACTIVE SIDE UP (blue or white face) facing the lightbox shining down. Expose the plates to light for 2 minutes.

Alternatively, place the imaging plates within 8 inches of a lamp equipped with a lit 100-watt bulb for two minutes, minimum. The imaging plates are now completely erased and are ready for reuse.

To avoid scratching the imaging plates, DO NOT lay the imaging plate active ("blue or white") face down on a lighbox.

Note: Erasing time will vary depending on the quality and intensity of the erasing light. For more detailed information, see appendix B.

5.3 Infection control

Prior to use, the DenOptix QST I/O imaging plates must be placed in barrier envelopes to minimize the possibility of cross-contamination. With proper application and use of the barriers, it will not be necessary to routinely cold sterilize the imaging plates. After erasing the imaging plates, follow these directions:

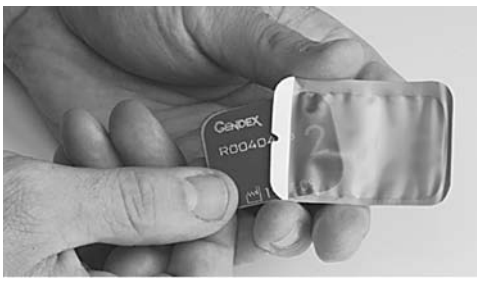


Figure 5-1
Insert the imaging plate into the barrier envelope, ensuring that the black side of the imaging plate can be seen through the clear side of the barrier envelope. Pay careful attention to the location of the orientation dot.

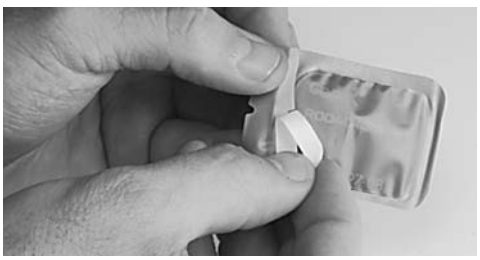


Figure 5-2
With the imaging plate completely inserted, seal the envelope by removing the adhesive strip and pressing the envelope closed. The imaging plate is now protected and can be used intraorally.

5.4 Taking an X-ray

Figure 5-3
Ensure the computer, monitor and DenOptix QST scanner are switched on and properly connected. The green LED indicates that the system is ready to scan.

Figure 5-4
Launch your imaging software. Refer to your Imaging Software User Manual for details (VixWin shown).

Intraoral imaging

Figure 5-5
Place an erased I/O imaging plate in the sealed barrier envelope and position in the patient's mouth. Make sure that the blue side (front of the barrier envelope and, therefore, front of the imaging plate) is toward the X-ray source. Wear appropriate gloves and protective attire.

We recommend the use of a positioning device. The orientation dot should be positioned toward the occlusal surface for periapical projections. Fold back the barrier prior to inserting it into the positioning device. This will ensure that the imaging plate is firmly held in place. Ensure that the imaging plate (not the barrier) is in the center of the aiming ring. Expose the X-ray in the usual manner. Exposure settings should be in accordance with Section 5.1.

Figure 5-6
Wearing gloves, remove the imaging plate in the barrier envelope from the patient's mouth. Wipe off any excess saliva with a paper towel. Disinfect the barrier envelope by dipping it into a cold sterilant solution, if desired.

After each exposure, open the barrier envelope at the "V" cut in the center of the packet, with a steady pull, and let the plate fall into the transfer container (Dark Box provided with the system).

At the end of the intraoral examination, remove and dispose of gloves and move to a semi-darkened room or area (see Section 4.8). Remove lid and begin the process of loading the imaging plates.

Do not touch the transfer container with contaminated gloves.

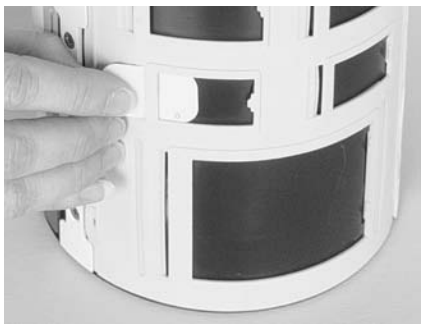


Figure 5-7
Remove your gloves and wash any powder from your hands. Mount the I/O imaging plates onto the carousel by sliding the right side of the imaging plate into the correct size I/O mounting hole in the carousel. Ensure that the blue side faces out.

Repeat until all I/O imaging plates are mounted.

Figure 5-8
Open the carousel well cover on the DenOptix QST scanner and insert the carousel. Close the lid. You are now ready to scan your I/O imaging plates, as outlined in Section 5.5.

Panoramic/cephalometric imaging

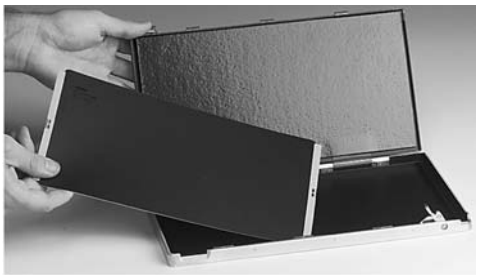


Figure 5-9
Place the erased panoramic or cephalometric imaging plate into the cassette with the white side pointed toward the tubehead.

Insert the cassette into the panoramic or cephalometric unit and expose in the usual manner.

Figure 5-10
With the EO/CH carousel you can scan 4 #2 size imaging plates, 2 #0 size and 1 #4 size imaging plate. Follow the steps previously outlined for intraoral imaging but mount the I/O imaging plates on the panoramic carousel.

When scanning a Pan or Ceph plate, rotate the knob in the direction of Pan or Ceph. When no pan or ceph is loaded, rotate the knob in the direction of "NO PAN or CEPH".

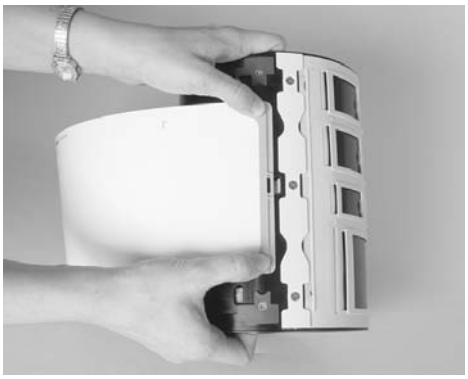


Figure 5-11
In a semi-darkened room (see Section 4.8), open the cassettes. With the white surface pointed away from the carousel, insert one side of the imaging plate under the edge of the panoramic or cephalometric imaging plate clip. Push with your thumbs until you hear a "click." NOTE: If the IP does not click into place, slide the IP to one side then the other until it clicks into place.
Panoramic shown.

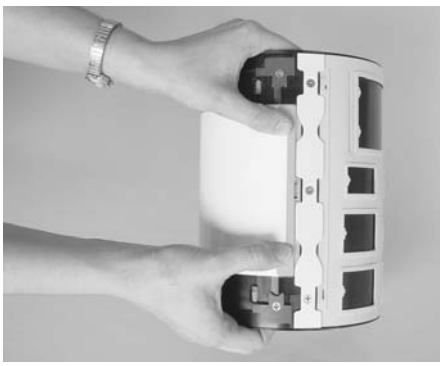


Figure 5-12
Wrap the imaging plate around the carousel and push the free end under the edge of the other clip. Push until you hear a "click."
Panoramic shown.

Figure 5-13
Open the carousel well cover on the DenOptix QST scanner and insert the carousel. Close the cover. You are now ready to scan your panoramic or cephalometric imaging plate.

5.5 Scanning the imaging plate

Figure 5-14
Once the scanner has been loaded and the patient file has been opened, click on the scanner icon on the imaging software toolbar. The software will automatically sense whether an FMX, EO or Ceph carousel is loaded.

Figure 5-15
When you scan a carousel, you can select from several options (subject to change, depending on the imaging software used).

It is possible to select how many plates to scan, and what size.

Plates can be arranged and saved to customized templates. You can select the plates by simply clicking the appropriate plate. The plates in black will be skipped (not acquired).

You can choose between 150, 300, and 600 dpi. Scan time will be longer as you chose higher dpi. Make the appropriate choice by clicking on one of the combinations and then clicking on "scan".

NOTE: The more specific you are, the faster the scan time will be. For example, scanning the top row takes less than 30 seconds at 300 dpi. Scanning 20 imaging plates at 300 dpi. takes approximately 75 seconds.

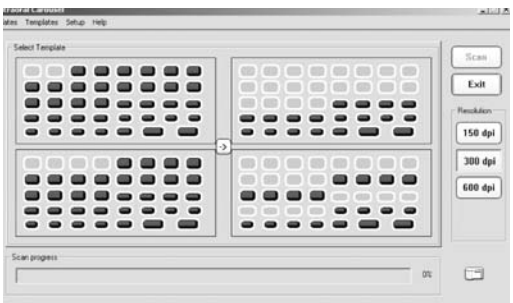


Figure 5-16
The last four templates scanned will be saved for quick retrieval by simply clicking the "T" in the lower right as shown in Figure 5-16. You can also save templates by selecting "templates" and save. After you name the template, you can retrieve this template by selecting "Templates" and "Load". A window box will appear requesting the name of the template to load.

Figure 5-17

The procedure for scanning a panoramic/cephalometric plate is the same as for the intraorals.

It is possible to select how many plates to scan, and what size. As with intraorals, you can choose between 150, 300, and 600 DPI. Scan time will be longer as you choose higher DPI. To switch between panoramic and cephalometric, click on the "P" or "C" symbol in the lower right hand corner. To change between inch and metric, click "IN" or "CM".

Choose your imaging plates by clicking on each of the imaging plate boxes you want to acquire and then clicking on "scan".

The plates in black will be skipped (not acquired).

To save the template, click on the template menu choice and save.

When the scan is complete, the I/O images will appear on the screen.

Note: if an error occurs during the scan, the scanner will stop. Follow the troubleshooting guidelines to start scanning again. If the resulting image is not diagnostic, erase the imaging plate and start again.

5.6 Preparing for the next patient

Once scanning is complete, it is time to get ready for the next patient.

Cross-contamination

There is no reason to routinely sterilize imaging plates unless you believe they have been contaminated. If an imaging plate has touched a contaminated surface, wipe it gently with lint-free gauze dampened with a cold sterilant as recommended by the manufacturer. DO NOT SOAK. Two percent (2%) Gluteraldehyde solutions will not damage the imaging plate if used as described. IMAGING PLATES CANNOT BE AUTOCLAVED.

If a carousel has touched a contaminated surface, the intraoral imaging plate holders should be removed (see Section 7.1) and wiped with a cold sterilant solution. The remainder of the carousel can be sprayed with an aerosol disinfectant or soaked in a cold sterilant solution.

If the outside of the DenOptix QST scanner has been touched by a contaminated surface, it must be cleaned. BEFORE PROCEEDING, TURN THE SCANNER OFF AND DISCONNECT FROM THE POWER OUTLET. The outside of the scanner can now be wiped with a towel dampened with cold sterilizing solution and then allowed to air dry. DO NOT SPRAY OR SOAK THE SCANNER. If necessary, wipe the inside of the carousel well with a cloth very lightly dampened with cold sterilizing solution. NEVER SPRAY THE INSIDE OF THE CAROUSEL WELL. Be careful not to allow solvent into the DenOptix QST scanner, which could damage the electronics inside. Allow to air dry before connecting the power cord or turning the unit on.

It is the operator's ultimate responsibility to ensure that correct infection control procedures, consistent with those recommended by the Board of Dental Examiners, are followed and that effective cold sterilant and disinfecting sprays are used.

Follow the steps in Sections 5.2 and 5.3 to erase the imaging plate and protect it from cross-contamination. You are now ready to take an X-ray on the next patient.

5.7 Turning the DenOptix QST system on and off

The DenOptix QST System is designed to be left on continuously. The laser is only operational while the unit is actually scanning. If you wish to turn the system off, please remove the carousel and use the following procedure.

1. Wait until any scan in progress is complete and the green light is on.
2. Save any changes you have made and close down the imaging software (for example VixWin Pro software). To protect your data, frequently back-up your files.
3. Turn the power switch in the back of the scanner to the "Off" position.
4. Turn off all computer components following any instructions from the manufacturer.

If you live in an area of frequent thunderstorms or variable line voltages, you may want to turn the unit off on a more regular basis. An uninterruptible power supply (UPS) is recommended for areas with power quality issues.

Software operating instructions

6

The DenOptix QST imaging systems can operate with different imaging software. For example, VixWin imaging software from Gendex optimizes digital X-ray images from the DenOptix QST systems. Please refer to your Imaging Software User Manual and Installation Guide for detailed instructions.

7

Maintenance procedures

The DenOptix QST System is designed for many years of trouble-free operation. It is manufactured from the highest quality components to ensure excellent performance. Maintenance that can be performed by the operator is minimal.

7.1 Cleaning the system

If the scanner, imaging plates or carousel becomes contaminated, clean in accordance with the directions given in Section 5.6. If, however, a component merely becomes soiled, clean as follows:

Cleaning the scanner

Turn off the DenOptix QST scanner, as described in Section 5.7, before cleaning. Wipe the outside surfaces with a paper towel dampened with a cold sterilant solution or household, non-abrasive cleaner (window cleaner works well). DO NOT SPRAY OR SOAK THE SCANNER. Wipe the inside of the carousel well with a very slightly damp cloth. Be careful not to allow running or dripping solvents into the DenOptix QST scanner. This could cause damage to the electronics inside. Allow to air dry before plugging in or turning back on.

Cleaning imaging plates

Imaging plates should be handled carefully. For the best images, take care not to scratch them and keep them dust-free. Use the following procedure to clean them:

1. Use lint-free, 100% cotton gauze (not cotton balls). Gently wipe the cotton gauze over the dry imaging plate surface. Wipe back and forth and then in a circular motion.
2. To clean any remaining stains, dampen the gauze in anhydrous (water-free) isopropyl alcohol and wipe using the same motion as above.
3. Completely dry the surface by wiping with another piece of cotton gauze. Ensure that the imaging plate is completely dry before use.

Cleaning the carousel

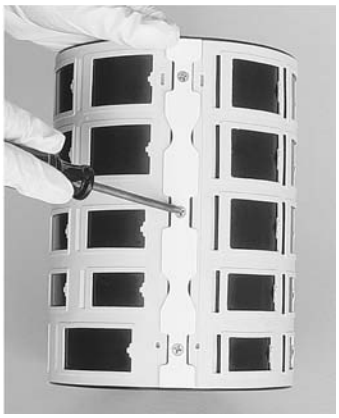


Figure 7-1
Remove the intraoral imaging plate holder from the carousel by removing the three screws along the vertical plastic retention piece. After removing the three screws, the intraoral plate holder will come free from the carousel.

Figure 7-2
Spray the soiled surfaces of the imaging plate holder and carousel with a general household non-abrasive cleaner or soap and water. Do not use strong alkaline or ammonia based cleaners. Wipe clean and allow to air dry.

Figure 7-3
Insert the dry imaging plate holder under the vertical plastic retention piece on the carousel. Slightly tighten the screws to hold the first side in place. Take the other side of the intraoral plate holder and place under the plastic retention piece and tighten the screws.

Cleaning the EO/CH (panoramic and cephalometric) carousel

Figure 7-4

To clean the EO/CH carousel, you will follow similar steps to the intraoral carousel. Remove the carousel imaging plate holder by removing the three screws of the plastic retention piece on both sides of the carousel. The imaging plate holder will easily come free.

Spray the carousel with a general household non-abrasive cleaning solution. Do not use strong alkaline or ammonia based cleaners.

Wipe clean and allow to air dry. If the intraoral imaging plate holder is soiled, remove it by removing both vertical plastic retention pieces by removing the three screws on each side and following the same instructions as for the intraoral image plate holder cleaning.

Clean with the general household non-abrasive spray or soap and water. Allow to dry completely before re-assembling. Re-assemble by placing one side of the imaging plate holder under the plastic retention device and tighten screws. Repeat step on the other side of the imaging plate holder, replace plastic retention device and tighten the three screws.

7.2 Operator maintenance

Scanner maintenance

The only part of the DenOptix QST scanner that may require operator maintenance is the fuse. If you experience any other service-related problem, contact your local Gendex dealer. Follow these directions to change the fuse.

Figure 7-5
Turn the DenOptix QST scanner off as per Section 5.7. Unplug the power cord and USB 2.0 cable.

WARNING: To avoid possible electrical shock, ensure that the power cord is unplugged.

Figure 7-6
Insert a small, flat tipped screwdriver into the top of the fuse cover on the back of the scanner. Pry the top of the connector open.

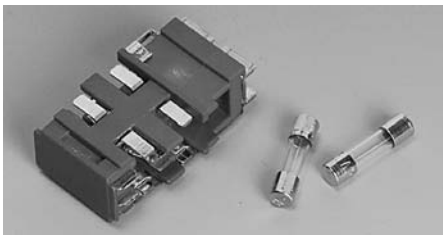


Figure 7-7
Remove the fuse holder. Change both fuses. Ensure that new fuses meet the following specifications: 250 V, 2 amp, Time Lag, High Breaking Capacity. Insert the fuses, REF 5101-0005, into the fuse holder.

Figure 7-8
Insert the fuse holder and close the cover. Plug the power cord back in and turn the system on as outlined in Section 5.7.

Carousel maintenance

The carousel from the DenOptix QST scanner can be maintained by the operator. If the intraoral imaging plate holder on an intraoral, panoramic or cephalometric carousel becomes damaged, it can be replaced by the operator. Order a replacement holder from your local Gendex dealer. The damaged holder can be removed and the new holder mounted as described in Section 7.1.

Imaging plate maintenance

The DenOptix QST imaging plates have no operator serviceable parts.

Lubrication

The DenOptix QST Digital System might occasionally require lubrication. If the scanner should start to squeak during scanning, please contact your local Gendex dealer. Do not position the DenOptix QST scanner in a dusty environment. Excessive dust levels can result in additional scanner service, beyond normal service intervals.

7.3 Troubleshooting

Trouble	Probable cause	Corrective action
No power No green light	Scanner not plugged in	Check power cord at outlet and at the connection on the back of the scanner. Turn on the scanner, then turn on the computer and monitor.
	Blown fuse	See Section 7.2
	Main power switch or power supply is bad	Call your service representative.
	Outlet does not have power	Ensure that the outlet is grounded and has power.
Lid is Locked	System is scanning	Wait for scanning to end before attempting to open the lid. DO NOT OVERIDE THE LOCKING MECHANISM DURING SCANNING.
	Power Failure or lack of power.	Unplug the scanner from the power source. Slide a thin tool or credit card into the gap between the lid and the scanner housing and simply depress the lock. You can then remove the carousel
Red, Green and/or Yellow LED(s) do not work; system operates normally	Defective LED	Call your service representative

Trouble	Probable cause	Corrective action
The Scanner does not initialize when the software is opened	The scanner has not been turned on	If the green power indicator light is off, switch on the DenOptix QST scanner per Section 5.7.
	The lid on the carousel well is open	Close the lid.
	The USB 2.0 cable between the scanner and computer is loose or defective.	Reconnect the cable. Check for tightness. Swap with a known good cable if possible.
	The computer does not recognize that the scanner is connected or the scanner has not been added to the Device Manager	Turn off the scanner and re-install the DenOptix QST systems software driver. Turn the unit on.
	There is a hardware problem with the DenOptix QST scanner.	Call your service representative
After scanning, no image appears on the monitor	There are no imaging plates on the carousel.	Ensure that the exposed imaging plate is properly mounted for scanning
	The imaging plate is mounted backwards on the carousel.	The imaging plates are to be mounted with the white or blue surface visible. Turn incorrectly mounted plates around and rescan
	The imaging plate was erased prior to scanning.	Ensure that imaging plates are mounted under low light conditions as outlined in Section 4.8
	Hardware failure.	Call your service representative.
	X-ray source failed.	Call your service representative.

Trouble	Probable cause	Corrective action
Image is too dark	Imaging plate has been overexposed	Adjust brightness with software. If this is not possible, retake image at lower exposure. See exposure guidelines Section 5.1.
Image contains ghost images or shadows	Imaging plate was not completely erased.	Increase the amount of time that is used to erase plates. Alternatively, increase the intensity of the light source. To test if an imaging plate is completely erased, simply mount an erased plate on a carousel and scan it. If no image is obtained, your procedure is effective at completely erasing imaging plates.
	Imaging plate was exposed with the back of the IP facing the tubehead You may notice the writing from the back of the plate on the image.	Insure the imaging plates are inserted properly into the barrier envelope and the proper orientation to the X-ray source is maintained
	Imaging plates have been stored in barrier envelopes for too long a period.	Do not store imaging plates in barrier envelopes for more than one week.
	Partial erasure of the image due to exposure to light during handling of the imaging plates.	Do not leave exposed imaging plates in well-lit areas. Even in the barrier envelope, some light penetrates and can partially erase the imaging plates. Transfer imaging plates from their protective barriers to the DenOptix QST scanner as quickly as possible using the Dark Box (within one hour of exposure).

Trouble	Probable cause	Corrective action
Image shows artifacts	The imaging plate surface is not clean and has dust, powder or stains on it. The surface may be scratched.	Clean the imaging plate as outlined in Section 7.1. If the plate is scratched or stained, do not use the plate again.
	The imaging plate was removed from the panoramic cassette too quickly, which resulted in a static discharge	Clean the imaging plate with anhydrous isopropyl alcohol AND remove from cassette more slowly.
The barrier envelope did not seal properly	After the protective strip covering the adhesive on the barrier envelope was removed, the adhesive was touched or picked up dirt.	Immediately seal the barrier envelopes after removing the adhesive strip.
Imaging plates fall out into the DenOptix QST scanner carousel well	The imaging plates have not been loaded properly. See Section 5.4 for more information.	Practice loading erased imaging plates in full daylight until you become familiar with the loading procedure. You will hear a "click" when the panoramic screen is loaded properly.
Extraoral plates don't stay on the carousel during scanning	Broken clips	Replace broken clips
The red light stays on and the scanner stops	Hardware failure	Call your service representative

7.4 Disposal of waste materials and inoperative parts

Disposal regulations vary from country to country. Therefore, it is difficult to give specific instructions on the disposal of DenOptix QST waste materials and inoperative parts. In general, we believe the following guidelines to be true.

Material	Items	Recycle?	Comments
Plastic	Barrier Envelopes Carousel Latches Holders for I/O Plates	No No No	Dispose of with other non-recyclable plastic items.
Aluminum	Housing, Optic Module Carousels Scan Engine Frame Carriage, Optic Module	Yes Yes Yes Yes	Remove all non-aluminum parts before recycling.
Storage Phosphors	I/O Imaging Plates Panoramic Imaging Plates Ceph. Imaging Plates	No No No	Contain barium, which may be regulated. Contact your local Gendex for more information on what to do with damaged imaging plates.
Other Materials	All Others	No	All other materials should be sent to a landfill.

8

Storage and shipment

8.1 Storage

The DenOptix QST System has been designed for long-term operation in a normal office environment. The system must be protected from adverse conditions such as excessive moisture, cold or heat. If the system is to be stored for a long period of time, pack the unit in its original carton. While in storage, keep at moderate temperatures and protect against moisture and humidity.

When you are ready to use the system again, unpack it and allow the scanner to come back to room temperature. Then, follow the guidelines outlined in Section 5.

8.2 Shipment

The DenOptix QST System is designed to be shipped in its original shipping container by normal commercial carriers. Ensure that the carousel has been removed from the scanner and that the carousel well is empty.

If the system is to be moved long distances or under adverse conditions, it should be protected. This can be accomplished by wrapping the DenOptix QST scanner in a plastic bag before putting it in the original packing materials.

If you are shipping the scanner, it is necessary to park the optics module in the center of travel prior to shipment. Contact your local Gendex rep for details.

9

Warranty statement

DenOptix QST scanner

The DenOptix QST Scanner and Carousels are designed expressly for use in a dental office environment and this warranty is not applicable to other uses. The scanner and carousels are warranted against defects arising from faulty materials or workmanship for two (2) years from date of purchase. Parts will be repaired or replaced at our option. The DenOptix QST Scanner and Carousels must be installed and operated in accordance with the Gendex written instructions furnished with the unit.

DenOptix QST imaging plates

The DenOptix QST Imaging Plates are designed expressly for use with the DenOptix QST scanner. DenOptix QST Imaging Plates will be replaced if defective in manufacturing or packaging only. With proper handling, DenOptix QST Imaging Plates are designed for years of effective use. They can, however, be damaged if folded, creased, scratched or dented, and, therefore no additional warranty is provided.

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Technical specifications

DenOptix QST scanner

Height	39.4 cm	15.5 in
Width	49.3 cm	19.4 in
Depth	27.4 cm	10.8 in
Weight (empty)	16 kg	35 lbs
Interface Cables	USB 2.0 cables	
Voltage	100-240 V AC	
Frequency	50/60 Hz	
Power	110 VA max.	
Laser Classification	Compliance per DHHS Radiation Performance Standards 21 CFR, Ch I, Subch. J+EN60825 Class 1 Laser Device	
Operating Conditions	15° to 35°C (59° to 95° F); 5%-95% RH NC	
Storage and Shipping Temperatures	-40° to 70°C (-40° to 158°F)	

Class I Grounded
For Indoor Use Only
Suitable for continuous operation

DenOptix QST intraoral imaging plates

	Size 0	Size 1	Size 2	Size 3	Size 4
I/O dimensions	22x35 mm	24x40 mm	31x41 mm	27x54 mm	57x76 mm
Recommended Dose	Significant reduction in relation to typical D-speed film depending upon type of X-ray device.				
Storage	Store in their clear plastic shipping box, at room temperature				
Operating and Storage Conditions	18° to 35°C (64° to 95° F); 5%-80% RH NC				

DenOptix QST panoramic/cephalometric imaging plates

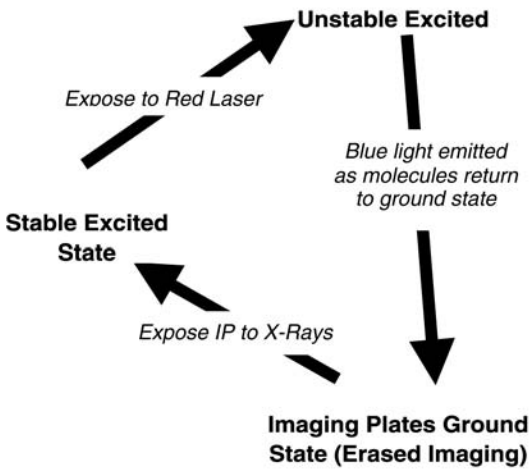
Dimensions	Pan: 5x12 in; 15x30 cm Ceph: 8x10 in; 18x24 cm
Recommended Dose	Equal to standard panoramic systems equipped with rare-earth intensifying screens (400 speed)
Storage	Store in their clear plastic shipping envelope
Operating and Storage Conditions	18° to 35°C (64° to 95° F); 5%-80% RH NC

11

Appendix

11.1 Appendix A: Storage phosphor technology

The DenOptix QST System produces high quality X-ray images at very low doses as compared to intraoral X-ray film. The imaging plates in the DenOptix QST Systems are much more efficient at capturing X-ray energy than film. This means that the timer on your intraoral X-ray source can be turned down to a very low level without affecting the image quality.


Unstable Excited
Expose to Red Laser
Blue light emitted as molecules return to ground state
Stable Excited State
Expose IP to X-Rays
Imaging Plates Ground State (Erased Imaging)

How storage phosphor imaging plates work

Each DenOptix QST Imaging Plate is made up of a very thin layer of tiny storage phosphor crystals that are bonded together and coated on a flexible sheet of plastic. These storage phosphor crystals have the ability to capture the energy of X-rays and store the pattern as a latent image (see diagram).

In essence, they act as an "energy trap," storing X-ray energy. The amount of energy stored is directly proportional to the amount of X-ray energy the crystal was exposed to.

The DenOptix QST scanner further excites the phosphor crystals to an unstable state by exposing them to a red laser. The phosphor crystals then release a blue light and return to their stable ground state. The DenOptix QST scanner reads this blue light and, with the imaging software, produces an image.

This process does not completely erase the imaging plate. Some crystals remain as "energy traps." This information can be erased by exposing the imaging plate to light. A few seconds of low levels of light will usually not effect the image quality. Once erased, the imaging plate can be re-exposed and the process can begin again. With proper handling, DenOptix QST Imaging Plates can be continually reused.

11.2 Appendix B: Lighting conditions for handling or erasing imaging plates

Without light, storage phosphor imaging would not work. The red light from the laser scanner excites the exposed imaging plates, causing them to emit blue light. After your computer interprets the blue light and changes it into a digital image, light is used to erase the residual information from the imaging plate.

Between X-ray exposure and scanning, however, one must be careful handling the imaging plates. An imaging plate should never be removed from its protective barrier and exposed to a strong source of light. This act would erase the latent image from the plate. Therefore, you must load imaging plates onto the carousel under controlled lighting conditions. The recommendations below have been developed to ensure that you obtain excellent image quality.

Recommendations on lighting conditions for loading carousels

Fluorescent lights

If loading can be accomplished in less than 60 seconds, the fluorescent lighting in the area should not exceed 20 lux. If loading will take longer than 60 seconds, the room conditions need to be darker. At 10 lux, the operator has about 5 minutes to accomplish loading.

Incandescent lighting

Incandescent lighting is not as efficient as fluorescent lighting at fading imaging plates. We recommend lighting conditions of around 20 lux. Under incandescent lighting, however, you have about 2 minutes to complete the loading process. If it takes longer than 2 minutes, decrease the amount of light to 10 lux.

Sunlight
Sunlight is efficient light for erasing imaging plates but it is not recommended that IPs are left exposed to sunlight for extreme periods of time. Additionally, it is very difficult to judge the intensity of sunlight. Loading carousels under sunlight must be avoided.

If you cannot darken your mounting area to 20 lux or less, contact your local Gendex representative for suggested mounting times.

Recommendations on lighting conditions for erasing imaging plates

In order to completely erase imaging plates, 99.5% of the image information must be removed. Scanning only removes part of the information. To completely erase imaging plates, follow the guidelines given below. It is important that you measure the light intensity with a light meter at the point where the imaging plate will be positioned. The intensity of light changes dramatically as you move away from the source. Erasing the imaging plates for periods of time longer than suggested does not harm them. A good place to store your imaging plates is under the erasing light source.

Fluorescent lights
We recommend using fluorescent lights for erasing imaging plates. A lightbox typically gives off between 1000 and 5000 lux. Measure your lightbox and use the lowest value to determine the erasing time. At 1000 lux, an imaging plate will be erased in 1 minute. At 2000 lux or more, 30 seconds is sufficient.

Incandescent lighting
At 1000 lux, an imaging plate will be erased in about 2 minutes. At 2000 lux or more, erase for 1 minute.

Sunlight
We do not recommend using it.

If you are unable to directly measure the light output from your erasing light source, or do not have an erasing light source greater than 1000 lux, use the practical test, below, to determine your erasing time.

Practical test

1. Completely erase five size 2 imaging plates by subjecting them to direct, intense light for about 20 minutes.
2. Scan the imaging plates. No image should appear on the monitor. If an image does appear, repeat step 1 with a more intense light source.
3. Place the imaging plates in barrier envelopes as described in Section 5.3.

4. Using the exposure conditions outlined in Section 5.1, expose each imaging plate. If possible, place an object, such as an extracted tooth, in the path of the X-ray beam.

5. Turn on your erasing light source. We recommend a light box or a minimum l00-watt incandescent light bulb (see Section 5.2).

6. Remove one imaging plate from its barrier envelope and place it with the blue side toward the light for 2 minutes.

7. Scan the imaging plate. If an image appears, the plate was not completely erased. Repeat step 6, adding a minute to the exposure time. Continue to repeat until no image appears on the monitor. Record the erasing time that resulted in no image. This is the time required to erase an unscanned imaging plate.

8. Repeat steps 1-4. This time, under low light conditions, remove the imaging plates from the barrier envelopes and mount them on a carousel. Scan the imaging plates.

9. Remove the scanned imaging plates and place them, in the dark, into a light-protected area (such as a light-tight drawer).

10. Now repeat steps 6 and 7, exposing one plate (blue side toward light) to the erasing light for 2 minutes, the next plate for 3 minutes, etc., until you find the point where no image appears on the monitor. This is the time required to erase a scanned imaging plate.

The time required to erase an imaging plate will vary depending on the quality and intensity of the erasing light source. It should be fairly easy to find a light source that will erase imaging plates in 2-3 minutes.

11.3 Appendix C: Optional printer

Because the DenOptix QST system can be interfaced with different applications software, and printer technology is constantly evolving, we can only suggest a list of suitable technical requirements for printers.

To interface with the PC, the printer must have a digital input and not a video (analog) input.

Using the standard Windows® drivers allows the use of the same printer for all other Windows applications (word processing, etc.).

Inkjet printers

Black and white or color hard copy. Printers should have a minimum of 600 dpi resolution and pseudo-randomic dithering.

We recommend using the photographic quality glossy paper and printing on the highest resolution setting available.

Thermal printers

Thermal printers print in shades of grey with at least 64 levels. Thermal printers use a special type of paper which guarantees a print life of about 3 years.

Dye sublimation printers

Suitable for high printing quality whenever the DenOptix QST System is used in combination with an intraoral camera.

Laser printers

If a Laser Printer is adopted, contact the Printer manufacturer or a representative to make sure that it can achieve at least 256 gray shades. Non medical grade Laser Printers may not be able to achieve a good image quality.

Application software

Please refer to the instructions in the application software for special information about printers.

11.4 Appendix D: If you need assistance

The DenOptix QST System is designed to provide years of trouble-free service, and carries a limited warranty. If you need assistance, first contact your local Gendex dealer. They have been trained to handle most technical service issues. If you cannot get the information you need there, simply call the Gendex office nearest to you.

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EC Declaration of Conformity

A. Product(s): DenOptix Quad Speed Digital Imaging Scanner in any of the following configurations:

See page 2

REF: DenOptix Quad Speed
Class: IIa

B. Reference Standards under which conformity is declared:

UL 60601-1	IEC 60601-1
CAN/CSA-C22.2 No. 601-1	IEC 60601-1-2
EN 50082	IEC 60825-1 (1994)
EN 55011	IEC 61000-4-2
IEC 61000-4-3	IEC 61000-4-4
IEC 61000-4-5	IEC 61000-4-6
IEC 61000-4-8	IEC 61000-4-11

C. GENDEX DENTAL SYSTEMS declares that the products described herein meet all the applicable Essential Requirements of the EC Medical Device Directive 93/42/EEC in Annex I. For Class IIa Digital Imaging Scanner products described herein, Annex II of the Medical Device Directive is followed, where applicable, and is certified by the British Standards Institute (BSI), Notified Body No. 0086.

Signed: _____ **Date:** 3/11/05
Title: Director, Quality Assurance & Regulatory Affairs

GENDEX

EC Declaration of Conformity (continued)

Product(s): DenOptix Quad Speed Digital Imaging Scanner in any of the following configurations:

DOIPQ5X12	DOIPQ15X30	DOIPQ8X10	DOIPQ18X24
DOQCOMBO1530	DOQCOMBO512	DOQEO1530	DOQEO512
DOQEOCAR	DOQFMX	110-0200G1	110-0200G2
110-0200G3	110-0200G4	110-0200G5	110-201G1
110-0201G3	110-0201G4		

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